Low-Intensity Pulsed Ultrasound Treatment for Scaphoid Fracture Nonunions in Adolescents

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Abstract

Background Treatment of scaphoid nonunion is challenging, leading clinicians to pursue innovation in surgical technique and adjunctive therapies to improve union rates.

Purpose The purpose of this study was to investigate the use of low-intensity pulsed ultrasound as an adjunctive treatment modality following surgical treatment of scaphoid nonunion in adolescent patients, for whom this therapy has not yet been FDA-approved.

Patients and Methods We performed a retrospective review of adolescent patients with scaphoid nonunion treated surgically followed by adjunctive low-intensity pulsed ultrasound therapy. All patients underwent 20 minutes of daily ultrasound therapy postoperatively until there was evidence of bony healing, based on both clinical and radiographic criteria. Final healing was confirmed by > 50% bone bridging on CT scan.

Results Thirteen of fourteen (93%) patients healed at a mean interval of 113 days (range 61–217 days). There were no surgical or postoperative complications. One patient developed heterotopic bone formation about the scaphoid.

Conclusions Our study suggests that low-intensity pulsed ultrasound therapy can safely be utilized as an adjunctive modality in adolescents to augment scaphoid healing following surgical intervention.

Level of Evidence Level IV, Case series

Keywords
- scaphoid fracture
- scaphoid nonunion
- pulsed ultrasound
- adolescents
- adjunctive therapy

Attempts by clinicians to maximize the healing potential of nonunions have led to the use of adjunctive treatment modalities such as low-intensity pulsed ultrasound therapy. The safety and efficacy of low-intensity pulsed ultrasound in the treatment of fracture nonunion has been previously investigated,[1–6] and this technology is approved in the United States by the Food and Drug Administration (FDA) for treatment of fracture nonunion in adults. Several recent studies of this adjunctive treatment modality have included a percentage of scaphoid fractures. Nolte et al reported on 29 cases of established fracture nonunion in a variety of anatomic locations, including five scaphoid fractures.[3] The majority of these cases were treated with prior surgery. Following failure of treatment, the nonunions were subjected to ultrasound therapy; 86% went on to healing in a mean time of 22 weeks. Of the scaphoid nonunions, four out of five demonstrated healing at a mean interval of 143 days. Similarly, Gebauer et al reported on 67 nonunions, including six scaphoid nonunions, treated with ultrasound therapy.[1] Healing occurred in 85% of the patients without additional surgical treatment. Rubin et al analyzed ultrasound prescription registry data to examine the effects of ultrasound on nonunion.[4] The registry subcategorized fracture nonunion by anatomic location, and the reviewing authors found that 101 out of 118, or 86%, of scaphoid fracture nonunions healed following ultrasound therapy. Rubin et al did not assess the registry data for other

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fracture nonunion–related treatment (bracing, cast, bone grafting, internal fixation, etc.).

Only one study has limited the scope of investigation of ultrasound therapy to scaphoid nonunion specifically. Ricardo et al performed a double-blinded randomized controlled trial of the effect of ultrasound on scaphoid nonunion healing following surgical treatment with vascularized pedicle bone grafting.[7] This study compared time to healing using clinical and radiographically defined criteria in 21 patients randomized to either ultrasound therapy or placebo therapy following surgical treatment. The investigators found a statistically significant reduction in time to healing in the intervention group: the average time to healing was 56 days in the ultrasound group versus 94 days in the control group. All patients were male and had an average age of 26.7 years, with the youngest being 17 years old. No further breakdown of patient demographics was published.

The purpose of the present study was to investigate the use of low-intensity pulsed ultrasound as an adjunctive therapy after surgical treatment of scaphoid nonunions in adolescent patients, as this modality has not been approved by the FDA for this purpose in this patient population (only for adults).

Methods

After receiving approval from our institutional review board, we performed a search of clinical records from two surgeons at a single institution from January 2005 to September 2013. We identified patients between the ages of 12 and 17 who had a diagnosis of scaphoid fracture nonunion and who underwent surgical repair followed by adjunctive low-intensity pulsed ultrasound therapy (►**Table 1**). We prescribed ultrasound bone stimulation therapy for all scaphoid nonunion repairs during this time period. Two patients were not included in this study, as they had no documentation of ultrasound use after their operative nonunion repair. Contraindications to the use of ultrasound therapy included active infection, pathological fractures, pregnancy, and skin lesions over the site of the ultrasound. None of the patients identified for this study had contraindications to the adjunctive use of ultrasound.

We initiated ultrasound treatment at the first postoperative visit after confirming appropriate healing for suture removal. We discussed the risks and benefits of ultrasound bone stimulation and obtained verbal consent from the patient and guardian to use this treatment modality. Each patient was instructed on the specific use of the ultrasound device in the office at this visit. An Exogen Ultrasound Bone Healing System (Smith and Nephew, Memphis, TN, USA) was used on each patient. This device delivers a 30-mW/cm^2 low-frequency (1.5-MHz) ultrasound. The manufacturer's recommended therapy consisted of 20 minutes daily use of the ultrasound device directly over the anatomic snuffbox until the fracture was healed. The ultrasound device is designed to be applied to the skin through a circular window in a fiberglass thumb spica cast or, more directly, by removing a wrist brace (depending on the type of immobilization present) (►**Fig. 1**). Patients were immobilized in a cast for at least 6 weeks. Then they were transitioned to removable wrist brace until radiographs showed evidence of bridging bone at the fracture site. We discontinued bracing and bone stimulation therapy when healing was confirmed on computerized tomography (CT) scan. Office visits occurred at ~4–6 week intervals until radiographic and clinical healing was present.

We defined radiographic healing as the presence of bridging bone on plain radiographs, which we then confirmed with CT scan. For the purposes of this study, greater than 50% bridging bone on successive cuts on CT scan confirmed

Table 1 Study group patient details

Patient #	Age (years)	Gender	Scaphoid fracture location	Bone grafting	Treatment outcome	Time to healing (days)
1	16	F	Proximal pole	Vascularized	Healed (CT)	130
2	15	M	Waist	Vascularized	Healed (CT)	90
3	15	M	Waist	Vascularized	Healed (CT)	104
4	17	M	Waist	Vascularized	Healed (CT)	106
5	17	M	Waist	Nonvascularized	Healed (CT)	217
6	16	M	Waist	Nonvascularized (iliac crest)	Healed (CT)	85
7	13	M	Proximal pole	Nonvascularized	Healed (CT)	79
8	15	M	Waist	Nonvascularized	Healed (CT)	78
9	16	F	Waist	Nonvascularized	Healed (CT)	154
10	15	M	Waist	Nonvascularized	Healed (CT)	70
11	16	M	Waist	Nonvascularized	Healed (X-ray)	61
12	13	M	Waist	Nonvascularized	Healed- on X-Ray	92
13	14	M	Waist	Nonvascularized	Not healed (CT)	*
14	16	M	Waist	None	Healed (CT)	195

Fig. 1 Clinical photograph of the modified thumb spica cast with built-in port window to allow application of low-intensity pulsed ultrasound therapy using the Exogen Ultrasound Bone Healing System (Smith and Nephew, Memphis, TN, USA).

radiographic healing. We defined clinical healing as a lack of tenderness at the scaphoid or anatomic snuffbox on physical exam. We designated time to healing as the period between surgical repair of the scaphoid nonunion and completion of radiographic and clinical healing. If there was a discrepancy between times to radiographic and clinical healing, we used radiographic healing for analysis. In addition to time to healing, we recorded complications including impaired wound healing, infection, and hardware-related complications during the treatment period. We then compared time to healing to historical controls for scaphoid nonunions treated with both nonvascularized and vascularized bone grafting.[8]

Results

We identified a total of fourteen patients, 12 male and 2 female. The age range of patients was 13 to 17 with a mean age of 15.3 years. Based on evaluation of radiographs at the time of patient presentation, three patients had reached skeletal maturity, whereas eleven patients were skeletally immature. There were 12 scaphoid waist fracture nonunions and 2 scaphoid proximal pole nonunions. Twelve patients had evidence of humpback deformity and five patients had evidence of avascular necrosis on preoperative imaging studies. The duration from injury to surgery could not be definitely quantified in this retrospective review, as many of the patients could not specify the exact date of their injury and were frequently referred for treatment from outside the group's practice after a diagnosis had been made. Surgical repair of the nonunion consisted of open reduction and internal fixation (ORIF) with a local pedicled vascularized bone graft (4 patients) or autologous cancellous bone grafting from the distal radius (9 patients). A single patient was treated with internal fixation without bone grafting. The surgical technique chosen for each patient was at the discretion of the treating surgeon. Thirteen patients had internal fixation using headless compression screws, and one patient had fixation with a volar scaphoid plate because of the location of the fracture and the use of a volar pedicled vascularized graft. Eight patients had additional scaphocapitate fixation, using a headless compression screw in seven patients and a Kirschner wire (K-wire) in one patient. All patients with scaphocapitate fixation had removal of the fixation at a mean time from surgery of 196 days (range 98–352 days).

Mean follow-up for the 14 patients was 326 days (range 61–745 days). Of the 14 patients included in this retrospective review, 13 achieved both clinical and radiographic healing (93%). Eleven patients had confirmed CT evidence of >50% bridging bone. Two patients did not have a follow-up CT scan to confirm final healing, although radiographs and clinical findings indicated healing at the final visit. Lastly, one patient, who underwent ORIF with local nonstructural autogenous bone grafting, failed to obtain radiographic healing at the final follow-up of 271 days following surgery.

The mean time to healing was 113 days, with a range of 61 to 217 days. The four patients who underwent pedicled vascularized bone grafting had a mean time to healing of 108 days. The single patient who underwent iliac crest bone grafting had a time to healing of 85 days (►**Fig. 2**). The eight patients who underwent local autogenous bone grafting

Fig. 2a–c Ulnar deviation PA view radiographs demonstrating: **a** Scaphoid nonunion of the right wrist in a 16-year-old patient, **b** Postoperative radiographs of the same patient following internal fixation and iliac crest bone grafting, with placement of thumb spica cast incorporating a window for ultrasound application, **c** Radiographs demonstrating interval healing of the scaphoid nonunion.

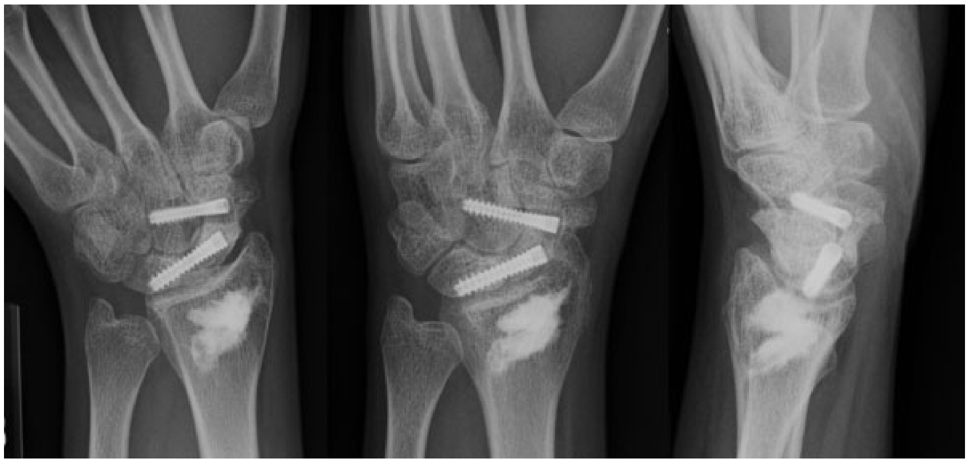

Fig. 3 One skeletally mature patient in the series developed heterotopic bone formation about the scaphoid following internal fixation and bone grafting for scaphoid nonunion. She has significant extension stiffness despite removal of hardware but has not wanted to undergo excision of the heterotopic bone.

achieved radiographic and clinical healing had a mean time to healing of 119 days. Of the three patients who were skeletally mature based on radiographs at presentation, one was treated with vascularized bone grafting, and the other two were treated with nonvascularized bone grafting. These two patients had a mean time to healing of 159 days. All three of these patients achieved clinical and radiographic healing. The 10 patients who were skeletally immature and went on to clinical and radiographic union had a mean time to healing of 99.1 days (►**Table 1**). One skeletally immature patient did not achieve radiographic and clinical healing and was subsequently treated at another institution and then lost to follow up.

We identified no wound complications, infections, skin reactions, soft tissue problems, or hardware complications in our study group. One patient who underwent ORIF with local autogenous bone grafting developed exuberant heterotopic bone about the scaphoid during healing (►**Fig. 3**). This patient had injured her wrist over 3 years prior to surgery and had undergone a scaphoid nonunion repair 5 months earlier with percutaneous bone grafting, which failed to progress to heal. She underwent a second surgery with repeat bone grafting and scaphocapitate and scapholunate screws as well as ultrasound therapy. After nonunion healing from her second surgery, she underwent an arthroscopically assisted partial excision of her scaphoid osteophyte and removal of her scaphocapitate and scapholunate screws 1 year later. On follow-up office visits, this patient had a painless wrist with limited range of motion and had returned to typical activities including competitive swimming.

Discussion

This retrospective study reports the results of a small, consecutive group of adolescent patients who underwent surgical treatment of scaphoid nonunion followed by adjunctive postoperative use of low-intensity pulsed ultrasound. The use of low-intensity pulsed ultrasound therapy is approved by the U. S. Food and Drug Administration for treatment of fracture nonunion, but only in adults. The mechanism of action of ultrasound therapy on bone healing is an area of ongoing research. Studies suggest that ultrasound therapy results in a host of changes, ranging from molecular modifications in ion channel permeability[9] and alterations in gene expression[10–12] to more mechanical effects such as increased blood flow[4,10,13] and the generation of strain secondary to acoustic perturbations.[14] The impact of these various changes in skeletally immature bone has not been fully elucidated, and the use of ultrasound therapy as an adjunct for treatment of fracture nonunion is off-label in adolescent patients. No previous studies have described any major complications resulting from the use of ultrasound therapy for fracture healing in adult patients. Nevertheless, because of the off-label use of this technology in adolescent patients, our objective with this current study was to evaluate the safety and efficacy of using this modality as an adjunctive therapy in this population. We discussed potential risks and benefits with both each patient and the patient's guardians prior to use.

As the use of ultrasound to stimulate bone healing in fracture nonunions is not routine, we should clarify why we elected to prescribe this modality for our patients. Scaphoid nonunions are among the most challenging nonunions to treat operatively, as the scaphoid proximal pole is completely intra-articular and suffers from limited, retrograde blood flow. Scaphoid nonunions treated surgically do not routinely heal despite heroic efforts to supply bone graft, vascularity, and rigid stability to the fracture site. Ultrasound bone stimulation does provide an adjuvant option to our surgical armamentarium. While we are not aware of a prospective randomized trial comparing surgical treatment of scaphoid nonunions with and without adjuvant ultrasound bone stimulation postoperatively, we did offer ultrasound to patients as an additional modality to further help achieve healing of their nonunion after surgery. The ultrasound bone stimulator used in this study comes with an approximate cost of $2,500 to $5,000 per patient, which is very high for an adjuvant treatment modality. Nonetheless, we wanted to offer patients every opportunity at our disposal to heal their scaphoid nonunions. We were successful in obtaining insurance coverage of the device in all of our patients (both privately and state-insured).

No clinically recognizable complications occurred, and 93% (13/14) patients demonstrated healing of the scaphoid nonunion at a mean time of 113 days following surgery. One male patient with open physes and a waist fracture nonunion at the time of presentation did not go on to radiographic and clinic healing after cancellous autografting. It is our best understanding that he followed our postoperative protocol as described above. It is possible that, despite his young age at the time of presentation (14 years), he could have benefited from a structural or vascularized graft as opposed to a percutaenously placed cancellous graft.

Our results with respect to rate of bony union are comparable to those reported in the recent literature. In a recent review of outcomes for adult scaphoid nonunion, Munk and Larsen reported an overall union rate of 80% after an average of 105 days in patients undergoing nonvascularized bone grafting without internal fixation, 84% after an average of 49 days in nonvascularized bone grafting with internal fixation, and 91% after an average of 70 days in vascularized bone grafting with or without internal fixation.[15] This report was a review of published literature over a 75-year period and therefore has limitations common to these types of studies, including the inclusion of variable study designs and surgical techniques employed. In a recent clinical report, Waitayawinyu et al reported a union rate of 93% in 30 consecutive patients with scaphoid nonunion treated with vascularized bone grafting.[8] Average time to healing was 5.1 months (~155 days). Postoperative ultrasound was not reported as an adjunctive treatment in this series. The study group had a mean age of 24 with a range of 16–44 years of age, but results were not stratified by age. The literature contains numerous reports of scaphoid nonunion in adolescents and the skeletally immature,[16–23] but no large series. Chloros et al reported healing of scaphoid nonunion in skeletally immature patients following open reduction, bone grafting, and internal fixation at a mean time of 3.4 months (~103 days).[17]

With respect to time to healing, we observed an overall slower time to bony union in our treatment groups compared with adult patients summarized in the Munk and Larsen review[15] as well as the skeletally immature patients in Chloros's series,[17] but a faster time to bony union than in the patient cohort reported by Waitayuwinyu et al. One explanation for this difference may be the use of CT as an additional criterion for healing in our study. Both Munk and Larsen and Chloros relied on plain X-ray images alone for radiographic confirmation of healing, while Waitauwinyu also utilized CT for confirmation of scaphoid nonunion healing. The one published prospective randomized controlled study evaluating the use of low-intensity pulsed ultrasound following scaphoid nonunion repair had a faster mean time to healing than our study in both the interventional and control groups, 56 days versus 94 days, respectively.[7] However, all of these patients were skeletally mature, and all had vascularized bone grafting nonunion repair in addition to internal fixation with K-wires. Healing in this randomized study was defined both as a lack of clinical symptoms and as the presence of bridging cortices on plan X-ray images, which is not the most reliable way to confirm radiographic healing.

Our study has important limitations. First, it is retrospective and uncontrolled, which leads to bias. The treating surgeons determined the nature of the surgical treatment for each patient without using a specific protocol. Specifically, the decision to perform vascularized versus nonvascularized bone grafting was often dependent on the operative findings and introduces a bias with respect to the healing time in the two groups. There exists no consensus in the literature on the optimal surgical treatment of scaphoid fracture nonunion in adolescent or pediatric patients.[17,18,24–26] Therefore, treatment of these challenging problems remains essentially at the discretion of the treating clinician. Third, we also did not have a control group to evaluate directly whether ultrasound therapy favorably affects the rate of bony union or time to healing. As such, we cannot definitely comment on the efficacy of ultrasound in this diversely treated population of scaphoid nonunions. The small number of patients included in the study and the heterogeneous surgical treatment of the patients did not allow a statistical evaluation of the role of vascularized versus nonvascularized bone grafting or the impact of patient related variables toward healing.

This study reports the results of surgical repair of scaphoid nonunion in adolescent patients treated with the adjunctive use of postoperative low-intensity pulsed ultrasound therapy. We found adjuvant ultrasound therapy safe in our patient cohort of adolescent patients, with no clinically identifiable complications and with healing rates comparable to those previously reported in the literature. Further randomized controlled trials in adolescent and skeletally immature patients are needed to elucidate the true benefit of low-intensity pulsed ultrasound therapy in treatment of fracture nonunion.

Conflict of Interest
None

Ethical Committee Statement
This retrospective review was approved by our institutional review board.

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